OCT - 4 2001

K012127 1/2

510(k) Summary
for
PulseMaster Erbium Dental Laser System

1. SPONSOR

American Dental Technologies, Inc.
5555 Bear Lane
Corpus Christi, TX 78405

Contact Person: William S. Parker
Telephone: (248) 596-1514

Date Prepared: September 5, 2001

2. DEVICE NAME

Proprietary Name:	PulseMaster Erbium Dental Laser System
Common/Usual Name:	Dental Laser System
Classification Name:	Laser Surgical Instrument

3. PREDICATE DEVICES

- K983211, Centauri Er:YAG Dental Laser System, Premier Laser Systems, Inc.
- K992013, DEL2940 Dental Erbium Laser, Continuum Biomedical, Inc.
- K001527, Fotona Fidelis Er:YAG Laser System and Accessories, Fotona d.d.

4. INTENDED USE

The PulseMaster Erbium Dental laser System is intended for the removal of caries and cavity preparation for primary and secondary teeth, the modification and etching of enamel and dentin prior to acid etching, and the incision, excision, ablation, vaporization, and coagulation of soft tissue in oral and maxillofacial surgery including, but not limited to, gingival tissues. -new

K012127 2/2

5. DEVICE DESCRIPTION

The PulseMaster Erbium Dental Laser System is a solid state Er:YAG laser consisting of three internally connected subassemblies: the power supply, the water cooling system, and the Er:YAG pump cavity and resonator assembly. Delivery is via a fiber optic with a sapphire contact tip. The laser delivers up to 400 mJ per pulse, with pulse repetition rates ranging from 10 to 60 Hz and an average power of up to 7.5 Watts.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The PulseMaster Erbium Dental Laser System has the same intended use and the same or substantially equivalent technical specifications and mechanism of action as compared with the named predicate devices. All of the devices are indicated for both hard and soft tissue applications in dental procedures and oral maxillofacial surgery. All of the devices utilize an Er:YAG solid state laser source operating at a wavelength of 2.94 microns, fiber delivery systems with contact tips, and operating parameters within the same ranges as the PulseMaster Erbium Dental Laser System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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American Dental Technologies, Inc.
c/o Ms. Sheila Hemeon-Heyer, JD, RAC
Senior Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K012127
Trade/Device Name: PulseMaster Erbium Dental Laser System
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and dermatology
Regulatory Class: II
Product Code: GEX, MXF
Dated: July 6, 2001
Received: July 9, 2001

Dear Ms. Hemeon-Heyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walk, MD

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012127

Device Name: PulseMaster Erbium Dental Laser System

Indications for Use:

The PulseMaster Erbium Dental laser System is intended for the removal of caries and cavity preparation for primary and secondary teeth, the modification and etching of enamel and dentin prior to acid etching, and the incision, excision, ablation, vaporization, and coagulation of soft tissue in oral and maxillofacial surgery including, but not limited to, gingival tissues.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012127